

21 CFR PART 117 - PCHF CASE STUDIES

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To Whom do 21 CFR 117 Subparts Apply?

Subpart A	117.4 Qualified Individual Training
Subpart B	Current Good Manufacturing Practice
Subpart C	Hazard Analysis and Risk-based Preventive Controls
Subpart D	Modified Requirements (117.201 for Qualified Facility) (117.206 for Unexposed Packaged Food Refrigerated for Safety)
Subpart E	Withdrawal of a Qualified Facility Exemption
Subpart F	Requirements Applying to Records That Must be Established and Maintained
Subpart G	Supply-chain Program

See PCHF Food Facility Type and Applicable Regulations Table (FSPCA FORM 0064)

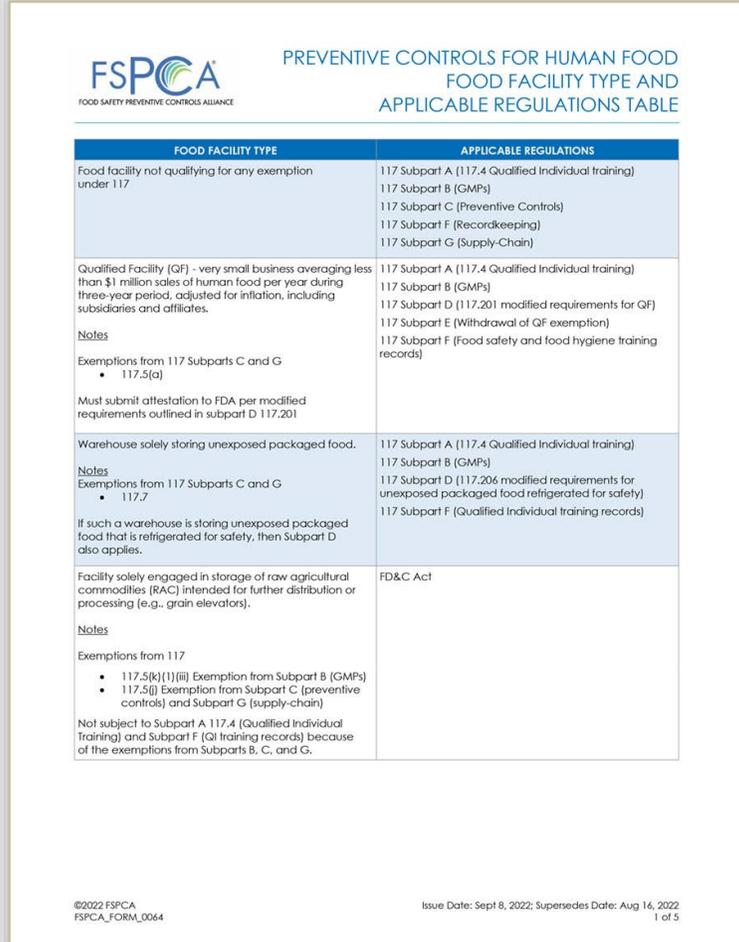


PREVENTIVE CONTROLS FOR HUMAN FOOD FOOD FACILITY TYPE AND APPLICABLE REGULATIONS TABLE

FOOD FACILITY TYPE	APPLICABLE REGULATIONS
Food facility not qualifying for any exemption under 117	117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart C (Preventive Controls) 117 Subpart F (Recordkeeping) 117 Subpart G (Supply-Chain)
Qualified Facility (QF) - very small business averaging less than \$1 million sales of human food per year during three-year period, adjusted for inflation, including subsidiaries and affiliates. <u>Notes</u> Exemptions from 117 Subparts C and G <ul style="list-style-type: none"> • 117.5(a) Must submit attestation to FDA per modified requirements outlined in subpart D 117.201	117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart D (117.201 modified requirements for QF) 117 Subpart E (Withdrawal of QF exemption) 117 Subpart F (Food safety and food hygiene training records)
Warehouse solely storing unexposed packaged food. <u>Notes</u> Exemptions from 117 Subparts C and G <ul style="list-style-type: none"> • 117.7 If such a warehouse is storing unexposed packaged food that is refrigerated for safety, then Subpart D also applies.	117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart D (117.206 modified requirements for unexposed packaged food refrigerated for safety) 117 Subpart F (Food safety and food hygiene training records)
Facility solely engaged in storage of raw agricultural commodities (RAC) intended for further distribution or	FD&C Act

PCHF Food Facility Type and Applicable Regulations Table (FORM_0064)

- Available on [FSPCA website](#) and [PCHF Lead Instructor Portal](#)
- PDF can be shared with course participants
- FSPCA Home Page:
<https://www.ifsh.iit.edu>



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Warehouse solely storing unexposed packaged food. Notes Exemptions from 117 Subparts C and G • 117.7 If such a warehouse is storing unexposed packaged food that is refrigerated for safety, then Subpart D also applies.	117 Subpart A (117.4 Qualified Individual training) 117 Subpart B (GMPs) 117 Subpart D (117.206 modified requirements for unexposed packaged food refrigerated for safety) 117 Subpart F (Qualified Individual training records)
Facility solely engaged in storage of raw agricultural commodities (RAC) intended for further distribution or processing (e.g., grain elevators). Notes Exemptions from 117 • 117.5(k)(1)(iii) Exemption from Subpart B (GMPs) • 117.5(j) Exemption from Subpart C (preventive controls) and Subpart G (supply-chain) Not subject to Subpart A 117.4 (Qualified Individual Training) and Subpart F (QI training records) because of the exemptions from Subparts B, C, and G.	FD&C Act

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SCENARIO 1

PBnJay Corporation

- Processing facility located on berry farm in Lehigh Acres, FL
- Manufacturer of fruit juice-based jellies, sugar-free jellies, peanut butter, cashew butter, and sunflower seed butter
- No related companies
- Incoming raw materials for the various butters are received through interstate commerce including the jars and lids
- Incoming raw materials for the jelly products are sourced locally including the jars and lids
- Distribution of jelly and butter products to retailers in AL and MS
- Total sales \$800,000 annually

21 CFR 117	Subject	Exempt
Subpart A (QI)	X	
Subpart B	X	
Subpart C		X
Subpart D	X	
Subpart F	X	
Subpart G		X

Qualified Facility

- Very small farm mixed-type facility averaging < \$1 million sales of human food per year during three-year period, adjusted for inflation
- Does not get 117.5(h)(3) exemption b/c not conducting low-risk manufacturing/processing activity/food combinations
- Subject to modified PC requirements outlined in 21 CFR 117.201 (Subpart D) (submitting attestations to FDA)

SCENARIO 2

Healthy Food Markets, Inc.

- Central Kitchen in Oakland, CA
- Produces variety of nut butters and sliced produce items
- Distribution to 3 company-owned retail stores in Bay Area
- The Central Kitchen has 50 full-time employees and 30 part-time employees
- Total employees at Corporate, the Central Kitchen and 3 stores equal 512 FTEs
- Company human food sales including all retail human food sales is > \$5,000,000 annually

21 CFR 117	Subject	Exempt
Subpart A (QI)	X	
Subpart B	X	
Subpart C	X	
Subpart D	N/A	N/A
Subpart F	X	
Subpart G	X	

Central Kitchen is a Food Facility

- Central Kitchen is subject to 117 including Subparts C and G. It is NOT a qualified facility.
- Does not meet definition of very small business averaging < \$1 million sales of human food per year during three-year period, adjusted for inflation (including any subsidiaries and affiliates)
- Does not meet definition of small business, a business (including any subsidiaries and affiliates) employing fewer than 500 FTE employees

SCENARIO 3

The People's Pickled Peppers

- Cooperative company in Pittsburgh, PA
- Produces variety of pickled peppers, packaged in glass jars
- Raw peppers are received from growers in CA Distribution to supermarkets throughout Midwest U.S.
- Sales of pickled peppers > \$5,000,000 annually

21 CFR 117	Subject	Exempt
Subpart A (QI)	X	
Subpart B	X	
Subpart C	X	
Subpart D	N/A	N/A
Subpart F	X	
Subpart G	X	

Acidified Food Processor

- 21 CFR 108/114 are regulations specific to Acidified Foods
- No exemptions from any subparts of 117

SCENARIO 4

PNW Fish Company LLC

- Seafood company in Seward, AK
- Produces salmon fillets, and fishmeal and fish oil from fish by-products
- Sockeye salmon received from harvesters in AK
- Distribution of salmon fillets to restaurants and supermarkets throughout U.S.
- Fish oil is distributed to a co-packer to be encapsulated as a dietary supplement
- Fishmeal is distributed for Animal Food use

21 CFR 117	Subject	Exempt
Subpart A (QI)	X	
Subpart B	X	
Subpart C		X
Subpart D	N/A	N/A
Subpart F	X	
Subpart G		X

Fish fillets and fish oil

- 21 CFR 123: Fish and Fishery Products
- 21 CFR 117: Subparts A, B, and F

Fishmeal for animal food

- 21 CFR 507 (cGMP & PC): regulation specific to Animal Foods
 - PNW Fish Company may choose to follow GMPs in either Part 117 or Part 507

Food Safety Plan Builder - free software application developed by FDA to help meet the requirements of the FSMA Final Rule for Preventive Controls for Human Food

<https://www.cfsanappsexternal.fda.gov/scripts/foodSafetyPlanBuilder/>

The screenshot shows the FDA website interface. At the top, it says "U.S. Department of Health & Human Services" and "U.S. FOOD & DRUG ADMINISTRATION". There is a search bar and a "SEARCH" button. Below the navigation menu, the page title is "Food Safety Plan Builder Download". The breadcrumb trail reads: "FDA Home > Food > Guidance & Regulation > Food Safety Modernization Act (FSMA) > Food Safety Plan Builder (FSPB)". The main content area features four circular icons: "FS" in a blue circle, a fork and knife in a white circle, "PB" in a dark blue circle, and a food box in a white circle. Below these icons, the text "FOOD SAFETY PLAN BUILDER" is displayed in large, bold, blue letters.



Farm Food Safety Plan

- 1. Farm Description**
- 2. Risks Assessment**
- 3. Establish practices to Reduce the Risks**
- 4. Document and Revise**
 - **Include SOPs and policies**
 - **Keep records**
 - **Revise your plan if it is not working or when practices change**



FARM FSP – RESOURCES

- Universities and extension programs
- Industry or commodity specific guidance
- Produce trade associations
- Federal guidance
- Independent organizations

FARM FSP – Template

- Example of farm food safety plan was developed by food safety specialists from College of Agriculture and Life Sciences at Cornell University
- Template is available for free on the Cornell Cals website:

<https://gaps.cornell.edu/educational-materials/farm-food-safety-plan-template/>

- **Modify the template to create your own unique FSP**

THANK YOU !